

# EXHIBIT 1



American Diabetes Association  
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# ADA/EASD/IDF Statement Concerning the Use of Incretin Therapy and Pancreatic Disease

Alexandria,  
June 28, 2013



Incretin therapy refers to medications such as GLP-1 receptor agonists and DPP-4 inhibitors, which are used to improve diabetes control and increase weight loss, either alone or in conjunction with other medications such as metformin or insulin. Extensive regulatory and clinical trials have examined the efficacy and effectiveness of these agents compared to both placebo and active therapies, including other members of this class of drugs.

These studies have shown universal superiority in glucose control and weight loss as compared to placebo, and at least equivalence, if not superiority, to active therapies such as sulphonylureas, TZDs, and long acting insulins. Over 80,000 subjects are currently enrolled in ongoing CVD outcome trials mandated by the U.S. Food and Drug Administration (FDA). These studies all have Data Safety Monitoring Boards reviewing patient level data for safety. One study, Savor, has completed and publically announced its primary findings without any suggestion of adverse outcomes. No studies have been terminated for safety concerns.

Recent epidemiologic studies, rodent studies, and a recent human autopsy study raised concerns that these agents (predominantly sitagliptin and exenatide, by virtue of their time on the market and thus longer patient exposure), may be associated with pancreatic changes ranging from pancreatitis to premalignant lesions. A June 2013 National Institutes of Health workshop reviewed the epidemiologic associations between diabetes and pancreatic carcinoma, showing an approximate 82 percent increased risk of malignancy associated with disease, independent of therapy. The FDA presented a thorough review of the pre-clinical pathology from submissions of all products on the market and under development, and three additional submissions requested, finding no concerns for pancreatic disease. Discussions of the human autopsy study identified significant study limitations and suggested alternative explanations for the findings reported by the investigators.

The American Diabetes Association, the European Association for the Study of Diabetes, and the International Diabetes Federation are committed to improving the lives of all people with diabetes, ensuring that a broad spectrum of safe and effective therapies is available to meet the needs of the diverse population affected by this disease. The three organizations firmly believe that people taking these medications, or those who may consider taking them, should be informed of all that is currently known about their potential risks and advantages in order to make the best possible decisions about their treatment and care, in consultation with their health care providers. At this time, there is insufficient information to modify current treatment recommendations. No patient should discontinue medication without first consulting with their health care provider. Their health care provider should take into account the patient's therapeutic responses and adverse events when considering whether to maintain or alter established therapy.

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The American Diabetes Association is leading the fight to Stop Diabetes and its deadly consequences and fighting for those affected by diabetes. The Association funds research to prevent, cure and manage diabetes; delivers services to hundreds of communities; provides objective and credible information; and gives voice to those denied their rights because of diabetes. Founded in 1940, our mission is to prevent and cure diabetes and to improve the lives of all people affected by diabetes.

For more information please call the American Diabetes Association at 1-800-DIABETES (1-800-342-2383) or visit [www.diabetes.org](http://www.diabetes.org) (<http://www.diabetes.org?loc=pressrelease>) .

Information from both these sources is available in English and Spanish.



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